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AB Science initiates a new phase 3 study with masitinib in Prostate Cancer, following encouraging survival results obtained in a phase 2 study

Masitinib is developed in 13 phase 3 studies, conducted in above 25 countries without any licensing agreement

AB Science SA (NYSE Euronext – FR0010557264 – AB), a pharmaceutical company specialized in research, development and marketing of protein kinase inhibitors (PKIs), announces the initiation of a phase 3 study to evaluate the safety and efficacy of masitinib in combination with docetaxel in first line treatment of metastatic Castrate Resistant Prostate Cancer (mCRPC).

I - Phase 3 in first line treatment of metastatic Castrate Resistant Prostate Cancer (mCRPC)

This is an international, multicenter, randomized, double blind, placebo-controlled, 2-parallel groups, phase 3 study to compare the efficacy and safety of masitinib in combination with docetaxel to placebo in combination with docetaxel in first line metastatic Castrate Resistant Prostate Cancer (mCRPC). The study will measure overall survival as a primary efficacy criterion. The phase 3 study has been authorized by competent authorities and will recruit 550 patients.

The decision to move to phase 3 follows encouraging results from an exploratory phase 2 study of 34 patients in second line treatment of metastatic Castrate Resistant Prostate Cancer. The phase 2 tested the combination of masitinib with docetaxel, which had an acceptable safety profile. Median overall survival in the masitinib plus docetaxel treatment-arm reached 18.4 months, which compares favorably to a meta-analysis of OS of 13.8 months in second line treatment of mCRPC before the recent arrival of Enzalutamide. With the arrival of Enzalutamide (median OS 18.4 months) the median OS reaches 14.4 months. Because docetaxel is the standard of care in first line treatment of mCRPC, and because the combination of masitinib and docetaxel has an acceptable safety profile, the phase 3 study was designed in first line treatment.

These data, although preliminary, are important since it is the fourth time an extended survival has been observed in clinical studies with masitinib in oncology as compared to standard-of-care. The first time was in imatinib-resistant GIST, with masitinib generating an additional 12 months median overall survival versus sunitinib. The second time was in first line treatment of pancreatic cancer, with two subpopulations having poor prognosis (i.e. patients with pain and patients with an aggressive genomic biomarker that flags a poor immune response) respectively reporting an additional median overall survival of 3 and 8 months for masitinib plus gemcitabine with respect to gemcitabine alone. The third time was in metastatic colorectal cancer with the combination masitinib plus FOLFIRI, with median OS reaching 14.5 months, which compares favorably to published results for FOLFIRI as a single agent at 12.5 months in patients with wild-type KRAS and 11.1 months in patients with mutant KRAS [Peeters et al. 2010].

Pr. Olivier Hermine, President of the Scientific Committee of AB Science indicated that “those four data converge to show that masitinib’s mechanism of action is capable of generating an important survival benefit in these cancers. AB Science reveals that masitinib in fact targets three cells to stimulate an innate

immune response, namely, mast cells, NK cells and macrophages. Unlike other tyrosine kinase inhibitors, masitinib acts also as an immune therapy, the benefit of which is to extend survival by controlling the aggressiveness, transformation and dissemination of the tumors."

II - Prostate cancer incidence

Prostate cancer is the fourth most common cancer in both sexes combined and the second most common cancer in men. An estimated 1.1 million men worldwide were diagnosed with prostate cancer in 2012, accounting for 15% of the cancers diagnosed in men, with almost 70% of the cases (759,000) occurring in more developed regions.

With an estimated 307,000 deaths in 2012, prostate cancer is the fifth leading cause of death from cancer in men (6.6% of the total men deaths).

III – Status of masitinib clinical development in human medicine

Masitinib is currently developed in 13 phase 3 indications (7 in oncology, 3 in inflammatory diseases, and 3 in neurodegenerative diseases) and 9 oncology indications in phase 2.

Clinical development has been initiated in more than 25 countries, without any licensing agreement. Therefore, AB Science has retained full ownership of masitinib.

Area	Indication	Study	Status
Oncology / Hematology	GIST in first-line treatment	Phase 3	On-going
	GIST in second-line treatment	Phase 3 confirmatory	On-going
	Metastatic melanoma with JM mutation of c-KIT	Phase 3	On-going
	Relapsed metastatic colorectal cancer	Phase 3	On-going
	Relapsed multiple myeloma	Phase 3	On-going
	Metastatic Castrate Resistant Prostate Cancer in first line	Phase 3	On-going
	Pancreatic cancer	Phase 3 confirmatory	To be initiated
	Relapsed metastatic non-small cell lung cancer	Phase 2	On-going
	Relapsed metastatic triple negative breast cancer	Phase 2	On-going
	Relapsed metastatic non triple negative breast cancer	Phase 2	On-going
	Relapsed metastatic melanoma	Phase 2	On-going
	Relapsed metastatic liver cancer	Phase 2	On-going
	Relapsed metastatic gastric cancer	Phase 2	On-going
	Relapsed metastatic head and neck cancer	Phase 2	On-going
	Relapsed glioblastoma multiforme	Phase 2	On-going
	Relapsed peripheral T-cell lymphoma	Phase 2	On-going
Non Oncology	Indolent Systemic Mastocytosis	Phase 3	On-going
	Non controlled severe asthma	Phase 3	On-going
	Refractory rheumatoid arthritis	Phase 3	On-going
	Alzheimer's disease	Phase 3	On-going
	Progressive forms of multiple sclerosis	Phase 3	On-going
	Amyothrophic Lateral Sclerosis	Phase 3	On-going

About masitinib

Masitinib is a new orally administered tyrosine kinase inhibitor that targets mast cells, important cells for immunity, as well as a limited number of kinases that play key roles in various cancers. Owing to its novel mechanism of action, masitinib can be developed in a large number of conditions in oncology, in inflammatory diseases, and in certain diseases of the central nervous system. Through its activity of inhibiting certain kinases that are essential in some oncogenic processes, masitinib may have an effect on tumor regression, alone or in combination with chemotherapy. Through its activity on the mast cell and certain kinases essential to the activation of the inflammatory cells and fibrosing tissue remodeling, masitinib can have an effect on the symptoms associated with some inflammatory and central nervous system diseases.

About AB Science

Founded in 2001, AB Science is a pharmaceutical company specializing in the research, development and commercialization of protein kinase inhibitors (PKIs), a new class of targeted molecules whose action is to modify signaling pathways within cells. Through these PKIs, the Company targets diseases with high unmet medical needs (cancer, inflammatory diseases, and central nervous system diseases), in both human and veterinary medicines.

AB Science has developed a proprietary portfolio of molecules and the Company's lead compound, masitinib, has already been registered for veterinary medicine in Europe and in the USA, and is pursuing thirteen phase 3 studies in human medicine in first-line and second-line GIST, metastatic melanoma expressing JM mutation of c-Kit, multiple myeloma, metastatic colorectal cancer, metastatic prostate cancer, pancreatic cancer, mastocytosis, severe persistent asthma, rheumatoid arthritis, Alzheimer's disease, progressive forms of multiple sclerosis, and Amyotrophic Lateral Sclerosis. The company is headquartered in Paris, France, and listed on Euronext Paris (ticker: AB).

Further information is available on AB Science website: http://www.ab-science.com/

This document contains prospective information. No guarantee can be given as for the realization of these forecasts, which are subject to those risks described in documents deposited by the Company to the Authority of the financial markets, including trends of the economic conjuncture, the financial markets and the markets on which AB Science is present.

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